IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

x

UNITED STATES OF AMERICA

ex rel. [UNDER SEAL],

Plaintiffs,

vs.

[UNDER SEAL],

Defendant.

Case No. 19-2501

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729, *ET SEQ.*

UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)

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ex rel. SW CHALLENGER, LLC,

Plaintiffs,

vs.

EVICORE HEALTHCARE MSI, LLC,

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Plaintiff, SW Challenger, LLC ("SW Challenger"), on behalf of the United States of America (the "United States"), brings this action pursuant to the Qui Tam provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended (the "False Claims Act"), against eviCore Healthcare MSI, LLC ("eviCore"). In support thereof, SW Challenger alleges as follows:

I. SUMMARY OF FACTUAL ALLEGATIONS

1. This is an action to recover damages and civil penalties on behalf of the United States arising from false and/or fraudulent records, statements and claims made, used or presented and/or caused to be made, used or presented by Defendant and/or its agents or employees under the Federal False Claims Act.

2. Under the Medicare Part C Program, known as Medicare Advantage, the federal agency that administers the Medicare program — the Centers for Medicare and Medicaid Services ("CMS") — contracts with private health-insurance companies (known as managed care organizations ("MCOs")), such as WellCare Health Plans, Inc. ("WellCare"), Passport, Blue Cross Blue Shield ("BCBS"), the Health Care Service Corporation ("HCSC"), Health Alliance Medical Plan ("HAMP"), and Moda Health, that operate health-insurance plans (known as "Medicare Advantage Plans") that cover Medicare beneficiaries. In sum, Medicare Advantage Plans are a type of Medicare health plan offered by a private company that contracts with Medicare to provide all of a beneficiary's Part A (Hospital Insurance) and Part B (Medical Insurance) benefits.

3. In administering government-funded Medicare Advantage Plans, MCOs are required to perform certain functions as set forth in their contractual agreements with CMS, including those related to prior authorization and utilization management and payment processing for outpatient and home health services.

4. CMS pays MCOs a capitated (per enrollee) amount to provide all Part A and B benefits. In addition, CMS makes a separate payment to MCOs for providing prescription drug benefits under Medicare Part D. Payments to MCOs are adjusted for enrollees' health status and other factors.

5. MCOs then share those payments with their sub-contractors and contracted medical providers.

6. CMS may terminate an MCO's Medicare Advantage contract for, among other things, the MCO carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of the Medicare Advantage program, and if the MCO commits or participates in fraudulent or abusive activities affecting the Medicare program including the submission of fraudulent data. 42 CFR § 422.504(h)(1); 42 CFR § 422.510(a)(4)(i).

7. All contracts between CMS and MCOs specify that any subcontractor who is delegated part of the MCO's functions must comply with all applicable Medicare laws, regulations, and CMS instructions. 42 CFR § 422.504(i)(4)(v).

8. CMS further requires that MCO executives certify that the patient data that they submit to CMS is true and accurate. CMS requires these signed certifications as a condition of payment. If a subcontractor generates the data, the subcontractor also must certify that its patient data is true and accurate. 42 CFR § 422.504(l)(3).

9. Defendant eviCore is purportedly in the business of providing utilization management services for Medicare Advantage Plans for outpatient and home health services. Defendant eviCore contracts with MCOs to provide utilization management services and review prior authorization requests.

10. Utilization management is a core MCO function in the administration of Medicare Advantage plans, making eviCore subject to Medicare Advantage requirements as articulated in Medicare Advantage regulations and related guidance. *See, e.g.*, Medicare Managed Care Manual Chapter 11 - Medicare Advantage Application Procedures and Contract Requirements 100.5 – Administrative Contracting Requirements, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c11.pdf ("CMS . . . view[s] contracts for. . . utilization management . . . to be administrative contracts subject to MA requirements as articulated in the MA regulation and related guidance."). As such, eviCore has agreed to comply with all applicable Medicare laws, regulations, and CMS instructions. *Id.*

11. One of the primary reasons that MCOs contract with third-parties like eviCore to perform these Government-mandated functions is to ensure that the MCO has in place procedures and systems to determine whether a particular medical procedure is reimbursable under Medicare Advantage. *See* 42 U.S.C. § 1395y(a)(1) ("Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

12. The entire purpose of this contractual arrangement, whereby eviCore provides sub-contracted medical review services to MCOs for the benefit of CMS, is to ensure that appropriate review procedures are in place and actually followed so as to reduce waste, fraud, and abuse within Medicare Advantage, and thus to ensure that medical procedures which are not reimbursable are denied.

13. Defendant eviCore knowingly accepted subcontracts from MCOs to take on the responsibility of providing CMS with prior authorization and utilization management for outpatient and home health services provided pursuant to Medicare Advantage. As such, eviCore was required to turn the same square corners in their dealings with MCOs as if they were dealing with the Government itself.

14. If eviCore agreed to contracts with MCOs to provide certain Government-mandated services, then eviCore's intentional failure to provide such services, or eviCore's use of a recklessly designed system that did not provide these services as called for by the MCOs' contracts with the Government, subjected eviCore to liability under the False Claims Act.

15. If eviCore failed to provide utilization management services and/or review prior authorization requests as contracted-for, and as a result an MCO approved treatments that were not reimbursable, that could result in patient harm and cost the Government a significant amount of taxpayer money.

16. Essentially, by entering into these agreements to provide services to MCOs, eviCore agreed to fulfill the role the MCO had in ensuring medically necessary treatments were approved and non-medically necessary treatments were denied under Medicare Advantage.

17. As relevant here, eviCore's contracts with MCOs include a key timing provision that requires eviCore to approve, partially approve, or deny in a timely fashion each request for prior authorization to deem services to a given beneficiary as reimbursable (each request also referred to as a "case"). In many instances, the turnaround time ("TAT") to process requests for prior authorizations is only 24 to 48 hours. Failure to meet its prescribed TAT will result in contractual penalties for eviCore.

18. Defendant eviCore, however, failed to hire sufficient staff to properly service its MCO subcontracts and meet the contractual timing requirements.

19. Rather, since at least November 2016, eviCore has engaged in fraudulent activities involving its role as the gatekeeper for determining whether requested services are appropriate and reimbursable. As detailed herein, through independent efforts to keep up with the high volume of prior authorization requests for services and to avoid contractual TAT penalties, eviCore instituted a scheme simply to "auto-approve" hundreds of cases on a daily basis, reflexively deeming those services as reasonable and necessary, even though there had been no appropriate evaluation of those cases, and in some cases, no actual human evaluation of those cases whatsoever.

20. Thus, to make up for its insufficient staffing, eviCore adopted procedures to automatically approve requested medical procedures without any meaningful clinical review or any limit on the scope of the procedure or the number of procedures approved. In layman's terms, for certain cases eviCore created a swinging gate prior authorization approval process that approved anything and everything that passed before it. In these circumstances, eviCore provided worthless services in exchange for its contractual payment to fulfill a necessary Government function that had been outsourced to MCOs and further subcontracted to eviCore.

21. Defendant eviCore specifically directed its medical personnel, internally called "Clinical Reviewers," including Relators, to "auto-approve" or "approve as requested" services in specific jurisdictions, for specific populations, and/or under specific healthcare plans, before and without any review of the propriety of the services.

22. These auto-approve directives, as described by eviCore to its reviewers, included, at various times, directives to Clinical Reviewers to "auto-approve" certain categories of services without any review.

23. Relators have direct personal knowledge of eviCore's conduct as it relates to the auto-approval of physical therapy treatment, but through their interactions with other reviewers working at eviCore, they learned that these procedures were not limited to physical therapy. Rather, upon information and belief, eviCore's auto-approval rubber-stamp had a large scope, including but not limited to the auto-approval of certain ***radiology services, cardiology procedures, interventional pain procedures, sleep therapy and laboratory management***. The risk of patient harm for services and procedures that are not medically necessary in these contexts could be significant.

24. In addition to the directives eviCore provided to its Clinical Reviewers, eviCore took further steps to ensure the approval of certain categories of requests by designing and implementing a data analytics system called "CorePath" that automatically approved certain requests in the absence of any human review.

25. In many cases, the MCOs were not aware of many of the auto-approval policies that eviCore had independently established. Rather, these auto-approvals were often established by eviCore solely for its own pecuniary benefit. For example, due to its lack of appropriate staffing and a desire not to pay for overtime work, eviCore (without MCO knowledge or approval) established auto-approvals for treatment requests submitted over certain holiday weekends.

26. By entering into these contractual arrangements with MCOs to provide utilization management and prior authorization services for Medicare Advantage, and thereby charging MCOs (acting as agents of CMS) for those services, eviCore was obligated to provide the contracted-for service. The failure to do so, without the MCOs' knowledge or approval, violates the False Claims Act.

27. Defendant eviCore's failure to perform its contracted-for utilization management and prior authorization services cost CMS and its MCOs a significant amount of money, and in certain cases, also created the opportunity for patient harm.

28. A specific example of potential patient harm caused by eviCore's actions includes the following:

a) ***Surgical***: for certain Medicare Advantage patients, Dr. Jaimie Clodfelter, D.O., an eviCore Medical Reviewer, told one of the relators in a telephone call that she is frequently asked to "sign-off" or auto-approve surgical requests even though Dr. Clodfelter is not a surgeon and does not have the professional clinical experience necessary to conduct a meaningful review of these requests.

29. Additionally, a new practice that eviCore has adopted is that when an MCO provides notice that the MCO will terminate eviCore's services, eviCore simply auto-approves everything from that departing MCO for internal cost saving purposes which violates the contract with the departing MCO and minimizes the utilization review required by the Government without disclosing such auto-approvals to the departing MCO. For example, on February 27, 2020, Marysue Agostini, Manager of MusculoSkeletal ("MSK") Specialized Therapy, indicated that due to BCBS IL Medicare's "de-implementation" (i.e., the contract with eviCore was ending) eviCore implemented auto-approval procedures.

30. Defendant eviCore failed to satisfy its contractual requirements and thus failed to provide necessary medical review functions for CMS by instituting these auto-approval policies.

31. As a result of its failure to provide any type of medical review on a large number of the cases that passed before it, Defendant eviCore knowingly provided worthless services of no

value to MCOs who stand in the shoes of CMS, thus causing MCOs to submit false claims for payment to the Government based on the assertion that eviCore was complying with the most basic and critical provisions of its subcontract.

32. Defendant eviCore thus knowingly failed to provide the medical review services that it was subcontracted to perform, thereby causing damages to the Government as CMS was not receiving the benefit of the contracted-for prior authorization and utilization management services that had been outsourced to MCOs and subcontracted to eviCore.

33. CMS would not have paid WellCare or other MCOs for prior authorization reviews, a key component of the MCOs' contracts with the Government, if it had known that the MCOs chosen subcontractor, eviCore, was providing worthless services.

34. One measure of potential damages in this case is the disgorgement of contractual payments made to Defendant eviCore, as the medical review process that eviCore had fraudulently implemented was not designed to actually perform the contracted-for services. The "reviews" eviCore did provide, often times automatic approval of anything put before it, were worthless and incapable of determining the propriety of the suggested medical care.

II. JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732(a).

36. This Court has personal jurisdiction over the Defendant because, among other things, the Defendant transacts business in this judicial district, and engaged in wrongdoing in this judicial district.

37. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendant transacts business within this judicial district, and acts proscribed by 31 U.S.C. § 3729 occurred in this judicial district.

38. Pursuant to 31 U.S.C. § 3730(b)(2), along with its submission of the original complaint in this matter, SW Challenger prepared and has served on the Attorney General of the United States and the United States Attorney for the Southern District of New York written disclosures of all material evidence and information currently in its possession.

39. This action is not based upon prior public disclosure of allegations or transactions in a federal criminal, civil, or administrative hearing, in which the government or its agent is a party. Nor have SW Challenger's allegations or transactions herein been publicly disclosed in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or in news media; or in any other form as the term "publicly disclosed" is defined in 31 U.S.C. § 3730(e)(4)(A).

40. To the extent there has been a public disclosure unknown to Relators of any of the allegations herein, Relators are the original source of those allegations within the meaning of 31 U.S.C. § 3730(e)(4)(B).

III. PARTIES

A. Plaintiffs

41. Plaintiff SW Challenger, a Delaware Limited Liability Company, brings this action on behalf of itself and the United States of America. Its principal place of business is c/o Seeger Weiss LLP, 55 Challenger Road, Ridgefield Park, NJ 07660. Among the members of SW Challenger are current and former eviCore employees (referred to herein collectively as "Relators" and individually as "Relator #1" and "Relator #2") with personal knowledge of the fraudulent

scheme alleged in this Complaint. The Relators possess personal knowledge and experience regarding eviCore's "auto-approve" activities, including personal contact with the employees and executives of eviCore who have planned, initiated and directed the violations of law alleged herein. The personal knowledge of SW Challenger is not distinct from that of the Relators.

42. Relators #1 and #2 is/was employed by eviCore as Clinical Reviewers, whose primary job responsibilities include reviewing physical therapy and occupational therapy treatment requests in the prior authorization context.

43. Relators' personal knowledge of Defendants' illegal conduct is supported by their own personal investigation undertaken to further develop and substantiate the allegations set forth in this Complaint.

44. Plaintiff, the United States of America, acting through the Department of Health and Human Services ("HHS"), and its Centers for Medicare and Medicaid Services, administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare"), which includes the Medicare Advantage component that is the subject of this lawsuit.

B. Defendant eviCore

45. Defendant eviCore is a Tennessee limited liability company with its principal place of business located at 400 Buckwalter Place Boulevard, Bluffton, South Carolina 29910.

46. eviCore is a direct successor to CareCore National ("CareCore"). In 2014, CareCore merged with MedSolutions, Inc., and the resulting entity rebranded itself as eviCore in 2015.

47. Between 2007 and 2013, CareCore engaged in Medicaid and Medicare fraud on a national scale, in which, as the Department of Justice reported, CareCore "blindly approved hundreds of thousands of medical procedures over a period of many years, leaving Medicare and

Medicaid to foot the bill."[1] From 2007 to 2013, CareCore improperly authorized over 200,000 outpatient diagnostic procedures, and, in 2017, paid a $54 million settlement based on that conduct. At least half of eviCore's current executive leadership team, including eviCore's Chief Executive Officer, were also in management positions at CareCore during the period 2007 to 2013.

48. As set forth in detail below, eviCore has continued its fraudulent scheme to overbill government health care programs.

49. Like its predecessor CareCore, eviCore contracts with private healthcare insurance companies to provide prior authorization and utilization management services pertaining to home health and outpatient services ordered by treating providers for the insurers' patient-beneficiaries.

50. Many of eviCore's private insurer clients are also carrier contractors under Medicare Advantage. Thus, eviCore provides prior authorization for services that are ordered for Medicare Advantage, many of which, as alleged herein, did not qualify as "covered services," yet were ultimately paid for by Medicare Advantage.

51. MCOs contracted, directly or indirectly, with eviCore.

52. MCOs delegated to eviCore the duty to make prior authorization decisions on home health and outpatient services, certain of which eviCore and MCOs knew would result in payment/reimbursement by Medicare Advantage for those services that were approved for beneficiaries.

[1] Acting U.S. Attorney Announces $54 Million Settlement of Civil Fraud Lawsuit Against Benefits Management Company for Improper Authorization Of Medical Procedures, (2017), https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-54-million-settlement-civil-fraud-lawsuit-against-benefits.

IV. LEGAL AND REGULATORY FRAMEWORK

A. The False Claims Act

53. The False Claims Act, 31 U.S.C. § 3729, as amended, provides:

> (a) **Liability for certain acts** –
>
> (1) In general – Subject to paragraph (2), any person who –
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(l).

54. "Knowingly" is defined by the False Claims Act as "mean[ing] that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information…." 31 U.S.C. § 3729(b)(1)(A).

55. Given its remedial purposes, the False Claims Act is interpreted broadly, and is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968).

56. The False Claims Act empowers a private person having information regarding a false or fraudulent claim against the Government to bring an action on the Government's behalf and to share in any recovery. 31 U.S.C. § 3730. The complaint must be filed under seal without

service on the defendant. *Id.* The complaint remains under seal to give the Government an opportunity to conduct an investigation into the allegations and to determine whether to join the action. *Id.*

57. Pursuant to the federal False Claims Act, the Relators seek to recover, on behalf of the United States, damages and civil penalties arising from the submission of false or fraudulent claims supported by false or misleading statements that Defendant caused to be submitted for payments, and that Defendant knew or should have known were going to be paid ultimately by government healthcare programs, including Medicare Advantage.

B. Medicare Advantage

58. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*, establishes the federal Medicare health insurance program for the elderly and disabled. Medicare operates by authorizing payments for inpatient and outpatient healthcare services to "providers," such as hospitals, skilled nursing facilities, outpatient rehabilitation facilities, and home health agencies. 42 U.S.C. §§ 1395cc(a), 1395x(u).

59. CMS administers Medicare on behalf of the Secretary.

60. For all services and items, Medicare coverage is limited to services that are medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1).

61. Under the Medicare Part C Program, known as Medicare Advantage, the federal agency that administers the Medicare program — CMS — contracts with private health-insurance companies (known as MCOs), such as WellCare, Passport, BCBS, HCSC, HAMP, and Moda Health, that operate health-insurance plans (known as "Medicare Advantage Plans") that cover Medicare beneficiaries.

62. Pursuant to Section 1874A of the Social Security Act, Medicare may contract with eligible entities, including MCOs, to perform certain functions or parts of those functions (or, to

the extent provided in a contract, to secure performance thereof by other entities), *see* 42 U.S.C. § 1395kk-1(a), such as payment functions (including the function of developing local coverage determinations, as defined in section 1395ff(f)(2)(B)), provider services functions, and functions relating to services furnished to individuals entitled to benefits under Medicare. 42 U.S.C. § 1395kk-1(a)(4).

63. Carrier contractors, including MCOs, are obligated to perform functions under the Medicare Integrity Program, 42 U.S.C. § 1395kk-1(a), which include any or all program integrity functions described in 42 C.F.R. § 421.304, which include "(a) [c]onducting medical reviews, utilization reviews, and reviews of potential fraud related to activities of providers of services…" and "(b) [a]uditing, settling and determining cost report payments for providers of services, or other individuals or entities. . . as necessary to help ensure proper Medicare payment." *See also* 42 C.F.R. § 421.200 (specifying carrier contractor functions).

64. Carrier contractors are required to "identify and verify potential errors to produce the greatest protection to the Medicare program." Medicare Program Integrity Manual § 2.1B.

65. In addition, carrier contractors, including MCOs, are "responsible for deterring and detecting fraud and abuse." Centers for Medicare and Medicaid Services Medicare Administrative Contractor Statement of Work § C.5.13.

V. EVICORE'S FRAUDULENT CONDUCT

A. Background on eviCore's Operations and Participation in Government Healthcare Programs

66. eviCore marketed, sold, and performed, and continues to market, sell, and perform, utilization management services to determine whether services that are covered and paid for by various government health insurance programs, including Medicare Advantage, are medically reasonable and necessary.

67. eviCore specifically contracts with third-party insurance companies, such as WellCare, to perform utilization management services by providing reimbursement determinations for services ordered by physicians and allied health professionals for hundreds of thousands of covered lives, including Medicare Advantage.

68. eviCore's Clinical Reviewers are trained in the use of utilization review criteria and rules provided to eviCore by MCOs (sometimes also referred to as the "Administrative Algorithm") to assess and to screen requests for prior authorization of evaluation and treatment procedures, which requests may have been processed previously by clerical intake department staff to collect demographic data. Clinical Reviewers consider the needs of individual patients and characteristics of the local delivery system when applying the clinical criteria. eviCore's Clinical Reviewers have the authority to certify (*i.e.*, approve) requests when the clinical information provided is consistent with the utilization review criteria and standards of practice.

69. The various schemes described herein, under which eviCore provided prior authorization for services in certain cases with no review at all, not only violated eviCore's own internal policies and procedures, but, more importantly, resulted in the submission of false claims for payment of services as eviCore was providing worthless services of no value as a subcontractor on a Government-contract.

B. eviCore's Scheme – In Detail

1. Proper Prior Authorization Approvals and Denials

70. If (1) a treating provider decides that a patient requires services and (2) that patient is a beneficiary of Medicare Advantage that contracts with an MCO that in turn contracts with eviCore, then the provider or his/her office must communicate with eviCore to obtain prior authorization for the service in order to ensure that the costs of the services will be covered by Medicare Advantage.

71. This communication can be accomplished by telephoning eviCore, faxing eviCore, or using eviCore's website. Regardless of which method the provider pursues, the information is entered into a request management system maintained by eviCore, called "Image One." The Image One system prompts users – eviCore intake personnel, eviCore Clinical Reviewers, or the providers themselves – to provide some of the points of demographic and clinical information necessary for eviCore to make reimbursement determinations.

72. In addition to "Image One," eviCore employs a data analytics system called "CorePath" to manage such requests. CorePath was created to automate prior authorization requests for a wide variety of populations, conditions and diagnoses.

73. This automation is not based on valid and reliable clinical information and evidence-based clinical guidelines, but rather on criteria that do not meaningfully determine the proper need and scope for services, such as the number of visits at issue.

74. CorePath was designed to rely on insufficient clinical information in an effort to auto-approve prior authorizations regardless of scope or necessity.

75. The Image One system contains a "journal" field, which tracks the lifetime of the request in narrative form. In the context of cases "in auto-approval status," Clinical Reviewers are required to enter information into the journal explaining their approval, that either (i) does not meaningfully analyze whether the request is properly reimbursable, or (ii) is itself fraudulent.

76. When a provider uses the eviCore website to make a request, the provider himself/herself enters clinical information directly into CorePath.

77. When a prior authorization request comes in by telephone or fax and contains the information necessary to "build" the request in the CorePath system, the request is routed to intake department personnel. The intake department personnel, who are non-clinical clerks, use the

information provided to "build" the request in the CorePath system in order to enable the system to generate a prior authorization decision.

78. When a prior authorization request comes in by telephone or fax and does not contain the information necessary to "build" the request in the CorePath system, the request is routed to Clinical Reviewers.

79. Under eviCore's legal and contractual obligations, after a request for a service for a beneficiary of Medicare or Medicaid is "built" in CorePath and/or Image One, eviCore Clinical Reviewers are supposed to review the request to determine whether the service is medically necessary before prior authorization will be approved. If the clinical information that was entered into Image One is insufficient for making such a determination, then Clinical Reviewers are supposed to place the case on hold and request additional information necessary for their decision.

80. Instead of providing a meaningful review in all such cases, however, eviCore has devised a variety of interlocking schemes designed to ensure fast TAT, high rates of approval for requests (including 100% approvals for certain types of requests), and low costs of review to eviCore – by sacrificing a proper review entirely in many categories of cases.

2. Directives to Manually Auto-Approve

81. One fraudulent method by which eviCore reduces the time and money spent on its review responsibilities is to direct Clinical Reviewers to ignore acceptable standards of clinical practice, evidence-based decision making, and their own clinical judgment, and to instead simply "auto-approve" all requests relating to certain providers, therapies, and populations.

82. Clinical Reviewers follow and implement these "auto-approve" directives by simply approving whatever services a provider requests, without making an independent determination on whether those services are medically necessary or reasonable.

83. These directives are relayed from eviCore management to Clinical Reviewers through training materials, emails, and conference calls.

84. In many cases, directives to "auto-approve" certain categories of requests originated from eviCore management. eviCore is motivated to employ auto-approval procedures for a variety of reasons, including handling high volumes of requests, staff shortages, and tight TATs.

85. Upon information and belief, eviCore's contracts with insurers include key timing provisions that require eviCore to approve, partially approve, or deny provider requests within a limited time-period or pay a penalty for the late response.

86. Auto-approval also keeps review costs down by enabling eviCore to assign Clinical Reviewers to review cases outside of their scope of practice and licensure. Because cases "in auto-approval status" are to be approved regardless of need, eviCore is able to assign Clinical Reviewers to approve cases in fields in which they lack experience, knowledge, and licensure, making eviCore's staff more flexible.

87. For example, on March 23, 2018, when eviCore was "short staffed on the [occupational therapy] side," Marysue Agostini, Manager of MusculoSkeletal ("MSK") Specialized Therapy, opened review of auto-approve occupational therapy requests to all pediatric physical therapy Clinical Reviewers. It is only the auto-approval system that makes it possible for eviCore to reassign staff in this way – the review eviCore would otherwise employ would require special training and knowledge that auto-approval schemes do not require.

88. Reinforcing that "auto-approval" relieves the Clinical Reviewer of performing a meaningful review, in an October 28, 2017 email, Agostini noted: "[A]ny Passport cases with a

start date of 11/1/17 or later requires medical necessity review. A start date of 10/31/17 or before remains auto approval."

89. Defendant eviCore has actual knowledge not only of the fact that its auto-approve scheme in general does not comply with statutory requirements, but also of many discrete examples where its "auto-approve" scheme led to inappropriate authorizations of services.

90. Agostini, in a November 8, 2017 email, herself described categories of cases that Clinical Reviewers "are auto approving that ask for significantly more visits than we would approve," and requested a set of "examples of egregious requests" to use in an upcoming meeting. Agostini specifically referenced in this email a case in which a Clinical Reviewer had "to auto approve 200 visits for an ankle sprain last week."

91. Furthermore, upon information and belief, eviCore's auto-approval rubber-stamp had a large scope beyond just physical therapy services, including but not limited to the auto-approval of certain radiology services, cardiology procedures, interventional pain procedures, and laboratory management.

3. CorePath and Image One

92. eviCore has also implemented artificial intelligence systems to further streamline the fraudulent auto-approve process.

93. The auto-approval scheme discussed above is less efficient than it might be: Although the scheme prevents Clinical Reviewers from approving, partially approving, or denying cases based upon an independent determination of need, the scheme still requires a *de minimis* level of involvement from Clinical Reviewers, who must identify the request as involving a category "in auto-approval status," and then manually approve the request. The necessity of this human input makes it difficult for eviCore to scale up its review process and increase its geographical coverage range, number of covered lives, and market share.

94. To respond to this need, eviCore designed its data analytics system, CorePath. By empowering this automated system to determine whether to authorize a requested service, eviCore saves itself significant costs, avoids the risk of TAT penalties, and makes its utilization management services "scalable" – by sacrificing the meaningful review it is obligated to perform.

95. In a phone call on September 14, 2017, Bruce Brownstein, eviCore's MSK Product Advisor, advised certain pediatric Clinical Reviewers that eviCore's expansion into new business lines would increase the number of requests submitted to eviCore to a point where it would be impossible for Clinical Reviewers making determinations to keep up with the greater volume. Brownstein further advised that he was working on a CorePath AI process specific to pediatric occupational and physical therapy, which would automatically approve the first and second such requests from a provider without any clinical review. The first provider request in this context would be automatically approved. To design criteria to enable the AI to handle the second request from a provider in this context, Brownstein sought, and received, assistance from certain pediatric Clinical Reviewers.

96. In an October 26, 2017 email, Rocco Labbadia, eviCore Vice President for Clinical Content and Integration, circulated a document describing the CorePath system. This document stated that CorePath would require providers to respond only to a "limited set of clinical questions" during the request for care, and explained CorePath's main goals: "[i]t is a primary intention of CorePath to ***resolve a high majority of episodes of care without requiring any practitioner review*** or additional clinical information outside of the pathways" (emphasis added). CorePath would avoid practitioner review by mechanically approving services requests on its own.

97. In a phone call on September 15, 2018, Labbadia represented that Brownstein's automated process for pediatric therapy requests was designed with the goal of making eviCore's

utilization review "scalable," *i.e.*, to enable eviCore to pursue more business lines and secure a greater market share. Labbadia stated that pediatric therapy requests had been targeted by this program because of the longer review time associated with such requests.

98. Even in those cases where the CorePath AI does not independently make the final decision as to authorizing a requested treatment, the Image One software still restricts the ability of Clinical Reviewers to conduct a meaningful review by, *e.g.*, making it technically impossible for the Clinical Reviewer to deny, or partially deny, certain categories of requests.

99. For example, on September 6, 2017, Agostini notified the review team that she had identified a logic problem in the Image One system that needed to be addressed: With regard to WellCare Florida Medicaid cases, which were subject to an "auto-approve" directive at the time, "the system should be preventing us from making adverse determinations," *i.e.*, denials, "[h]owever, this is not happening."

100. Similarly, in a March 7, 2018 email implementing a different review process for certain categories of WellCare cases that had been subject to auto-approval, Agostini noted that the change "will require an IT update as the system does not allow for these cases to be denied."

101. As of March 2019, eviCore has implemented CorePath logic processes to automatically authorize requests from healthcare providers including Affinity, Blue Cross Blue Shield, Passport, and WellCare, across states including, at least, Arkansas, Connecticut, Illinois, Kentucky, Louisiana, Maine, Missouri, Mississippi, New Mexico, New York, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas.

C. eviCore's Attempts to Whitewash its Auto-Approval Schemes

102. In early February 2019, eviCore began a process of whitewashing its internal review materials to remove or obfuscate references to automatic approval. At every stage of this process, however, eviCore made it clear to Clinical Reviewers that the replacement of the "auto-

approve" language with euphemisms was not intended as a substantive change to the auto-approve process, which eviCore directed its Clinical Reviewers to continue.

103. On February 22, 2019, Agostini emailed a small group of Clinical Reviewer supervisors, advising them that "we need to update our resources and remove any language of 'auto-approval,'" and providing substitute language, such as "approve as requested," and "approve up to the benefit limit" with which to update the Administrative Algorithm and Health Plan Guide, two documents Clinical Reviewers rely upon in evaluating prior authorization requests.

104. However, after these changes to the administrative algorithm and other job aids were implemented, on March 1, 2019, an announcement to reviewers stated that these updates to the Administrative Algorithm and Health Plan Guide were "minor updates to language that don't affect algorithm."

D. eviCore's Fraudulent Scheme Caused the Submission of False Claims and Loss to the Federal Treasury

105. Once a case has been approved by eviCore, the member receives the outpatient or home health service at the facility, the facility submits the bill to the payor, and the payor pays for the service. In the case of Medicare Advantage, the Government ultimately pays for the service.

106. Accordingly, the vast majority of services that resulted from eviCore's scheme were approved for payment, performed, and reimbursed, despite the fact that none of the auto-approved cases had been properly qualified as medically reasonable and necessary, as is required for government reimbursement.

107. As a result of eviCore's scheme, CMS paid MCOs and their subcontractor, eviCore, millions of dollars to perform prior authorization reviews which either never happened or were undertaken in a sub-standard, worthless fashion.

108. By virtue of the false or fraudulent claims for payment for worthless services that Defendant knowingly submitted or caused to be presented to the Government, the United States has suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

109. As a result of eviCore's fraudulent conduct, CMS has been paying and continues to pay millions of dollars annually for worthless medical review services which were and are not medically appropriate. At the very least, Defendant eviCore should be disgorged of the Government payments it has fraudulently received through its sub-contracts with MCOs.

COUNT I
Violation of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
United States of America ex rel. Challenger LLC vs. eviCore

110. Relator incorporates herein by reference each and every allegation of the preceding paragraphs of this First Amended Complaint as though fully set forth herein.

111. As a result of the foregoing conduct, eviCore knowingly presented, or caused to be presented, false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1)(A).

112. The claims relevant to this Count include all claims for payment submitted by MCOs to CMS for the above-referenced prior authorization services that eviCore either never rendered, or performed in a worthless fashion, which were caused to be submitted by virtue of eviCore's scheme directly to CMS.

113. Defendant eviCore caused the submission of such false claims for payment through their client MCOs, including WellCare, knowing that those private entities were agents for CMS, and knowing that eviCore's auto-approval prior authorization system violated a key audit function that had been delegated from CMS to MCOs and then sub-contracted to eviCore.

114. All such claims for payment that eviCore caused to be submitted were false because they were for worthless prior authorization services that were not properly undertaken per the clear terms of the contract between CMS and the client MCOs.

115. eviCore had knowledge of the falsity (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the MCOs claims' for payment to the Government because, in its role as utilization review manager for its insurer clients it had actual and constructive knowledge of the worthless services it was rendering as a result of its auto-approval process, and because, as utilization review manager for its insurer clients, eviCore was obligated by contract as well as under federal regulations to undertake a proper medical review of each case before it.

116. As a result of eviCore's actions as set forth above in this First Amended Complaint, the United States of America has been, and continues to be, severely damaged.

COUNT II
Violation of Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
United States of America ex rel. SW Challenger LLC vs. eviCore

117. Relator incorporates herein by reference each and every allegation of the preceding paragraphs of this First Amended Complaint as though fully set forth herein.

118. As a result of the foregoing conduct, eviCore knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

119. The claims relevant to this Count include all claims for payment submitted by MCOs to CMS for the above-referenced prior authorization services that eviCore either never rendered, or performed in a worthless fashion, which were caused to be submitted by virtue of eviCore's scheme directly to CMS.

120. The false or fraudulent records or statements underlying the false claims relevant to this Count include all false or fraudulent records or statements regarding eviCore's prior authorization approval process made by eviCore to its client MCOs, including WellCare, and adopted by the MCOs in communications with the Government in carrying out the scheme.

121. eviCore made false or fraudulent records or statements underlying the false claims to its client MCOs, including WellCare, knowing that the auto-approval process violated federal laws, that its client MCOs were private entities acting as agents for the federal and/or state governments, and that the worthless services rendered as a result of the auto-approval process would be material to the payment decision of the Government in regards to whether it would continue to contract with and pay its MCOs.

122. All such resulting claims for payment that eviCore caused to be submitted by its client-MCOs were false because eviCore's prior authorization process that incorporated auto-approve and CorePath AI schemes rendered eviCore's prior authorization services, and thus the services of its client MCOs, worthless such that the Government would not have otherwise paid for such fraudulent activity.

123. eviCore had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the falsity of its client MCOs' claims for payment to the Government because, in its role as utilization review manager for its insurer clients, it had actual and constructive knowledge of the fraudulent prior authorization practices that eviCore had adopted, and because as utilization review manager for its insurer clients, eviCore was obligated by contract as well as under federal regulations to ensure such prior authorization services were performed in a correct and medically appropriate fashion.

124. The United States of America, unaware of the falsity of the records or statements underlying the false claims caused to be made by eviCore, and in reliance on the accuracy of these records or statements underlying the false claims, paid its MCOs for eviCore's worthless services.

COUNT III
Violation of Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G)
United States of America ex rel. SW Challenger LLC vs. eviCore

125. Relator incorporates herein by reference each and every allegation of the preceding paragraphs of this First Amended Complaint as though fully set forth herein.

126. By virtue of the acts alleged herein, eviCore knowingly made, used or caused to be made or used false records or false statements that are material to an obligation to pay, transmit or return money to the Government.

127. As a result of eviCore's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $ 11,665 and up to $23,331 for each and every violation of 31 U.S.C. § 3729 arising from eviCore's unlawful conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Relators pray that judgment be entered against Defendant, ordering as follows:

A. That Defendant cease and desist from violating 31 U.S.C. § 3729, *et seq*.;

B. That civil penalties of not less than $ 11,665 and up to $23,331 per claim as provided by 31 U.S.C. § 3729(a) and adjusted for inflation be imposed for each and every false or fraudulent claim that Defendant caused to be submitted to the United States and/or its grantees, for each false record or statement Defendant made, used, or caused to be made or used that was material to a false or fraudulent claim, that three times the amount of damages the United States sustained because of Defendants' actions also be imposed;

C. That Defendant be enjoined from concealing, removing, encumbering, or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

D. That Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct;

E. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h);

F. That Relators be awarded all costs, including but not limited to, court costs, expert fees and all attorney fees, costs and expenses incurred by Relators in the prosecution of this suit; and

G. That Relators be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, SW Challenger demands a trial by jury of all issues so triable.

DATED: May 21, 2020

Respectfully submitted,

SEEGER WEISS LLP

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